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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/356,322	<b>Applicant(s)</b> SHALON ET AL.	
	<b>Examiner</b> BJ Forman	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 7-19,21-27 and 29-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-19,21-27 and 29-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed 30 December 2005 in which claims 7 and 21 were amended and claims 20 and 28 were canceled. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 12 January 2005, not reiterated below, are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 7-19, 21-27 and 29-40 are under prosecution.

### ***Priority***

2. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, Parent Applications 08/514,875; 08/477,809; and 08/261,388 upon which priority is claimed do not provide adequate support under 35 U.S.C. 112 for claims 14, 29, 35 and 38-39 of this application. Instant Claims 14 and 29 are drawn to "covalently bound DNA"; Claim 35 is drawn to "two fold change in the relative abundance"; and Claims 38-39 are drawn to "distinct gene sequences whose expression levels are specifically related to the differences between test cells relative to control cells". These elements are not supported by the parent application cited above. Therefore the effective filing date for Claims 14, 29, 35 and 38-39 is the filing date of Application No. 08/688,488 i.e. 30 July 1996.

### ***Claim Objections***

3. Claim 16 is objected to because of the following informalities: The claim is objected to because "polycationic" is misspelled.

Appropriate correction is required.

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***Claim Rejections - 35 USC § 112***

**35 U.S.C. 112: first paragraph**

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 7-19, 21-27 and 29-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In papers filed 26 September 2001, the recitation "400 or more" was added to the specification and independent claims. The new language was rejected under new matter by the previous examiner, but not reiterated in the most recent office action. IN papers filed 18 June 2002, Applicant asserts that the 400 regions is supported by the discussion at the top of page 10 and Fig 5-6. The passages have been reviewed but are not deemed to support the range of "400" or "400 or more". In contrast, the claimed 400 regions is deemed a subgenus of the range contemplated in the originally filed specification. The courts have stated that a generic disclosure does not support a subgenus range. Hence, the generic range taught in the specification does not support the newly claimed subgenus range of "400 or more".

"Thus, the written description requirement prevents an applicant from claiming subject matter that was not adequately described in the specification as filed. New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads)." (MPEP § 2163).

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35 U.S.C. 112: second paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 7-19, 21-27, 29-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7-19 and 38 are indefinite in Claim 7 for the recitation “about 400 or more” and “at least about 50 subunits”.

Claim 8 is indefinite for the recitation “at least about 10,000/cm<sup>2</sup>”.

Claim 9 is indefinite for the recitation “at least about 2500/cm<sup>2</sup>”.

Claims 21-33 and 40 are indefinite in Claim 21 for the recitations “about 400 or more” and “at least about 400”.

Claim 22 is indefinite for the recitation “about 10,000 regions/cm<sup>2</sup>” or more.

Claim 23 is indefinite for the recitation “about 2500/regions/cm<sup>2</sup>” or more.

Claims 34-35 and 39 are indefinite in Claim 34 for the recitations “about 400 or more” and “at least about 50 subunits”.

It is vague and indefinite what is meant by the phrases listed above e.g. “about 400 or more” and “at least about 50 subunits”. The phrases “or more” and “at least” typically indicate a minimum point. The phrases “or more” and “at least” however, are contraverted by the term “about” which implies that values above and below 400 regions and 50 subunits are permitted. Further, the extent of variance permitted by “about” is unclear in this context. Since regions and subunits (nucleotides) are whole numbers, “about 16” cannot mean from 14.4 to 17.6 because regions and nucleotides cannot be split in half. Therefore, it is also unclear if “about 50” simply includes 49 or if it also includes 35-40 as well. In Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (CAFC 1991), the CAFC stated, “The district court

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held claims 4 and 6 of the patent invalid because their specific activity limitation of "at least about 160,000" was indefinite". After review, the CAFC states "We therefore affirm the district court's determination on this issue." Thus, the CAFC found the phrase "at least about" indefinite where the metes and bounds of the term were not defined in the specification.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 7-19, 21-27, 29-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Fodor et al (U.S. Patent No. 6,610,482 filed 6 December 1990).

Regarding Claim 7, Fodor et al disclose (and claim) a substrate comprising a microarray of DNA having a density of 400 or more regions/cm<sup>2</sup> wherein the DNA sequences are about 50 subunits in length (Claims 40 & 56).

Regarding Claim 8, Fodor et al disclose the substrate wherein density is at least 10,000 regions/cm<sup>2</sup> (Claim 42).

Regarding Claim 9, Fodor et al disclose the substrate wherein density is at least 2500 i.e. 10,000 regions/cm<sup>2</sup> (Claim 42)

Regarding Claim 10 Fodor et al disclose the substrate wherein the substrate is glass (Claim 61).

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Regarding Claim 11 Fodor et al disclose the substrate wherein the substrate is non-porous i.e. glass (Claim 61).

Regarding Claim 12, Fodor et al disclose the substrate wherein the surface is hydrophobic e.g. plastics or hydrophobic linkers (Column 17, lines 14-48).

Regarding Claim 13, Fodor et al disclose the substrate wherein the surface comprises one or more functional groups e.g. silyl, hydroxyl, carboxyl, amine aldehyde, sulhydryl (Column 17, lines 24-29).

Regarding Claim 14, Fodor et al disclose the substrate wherein the DNA sequences are covalently bound (Column 8, lines 21-27).

Regarding Claim 15, Fodor et al disclose the substrate wherein the DNA sequences are non-covalently bound (Column 8, lines 21-27).

Regarding Claim 16, Fodor et al disclose the substrate wherein the DNA sequences are non-covalently bound (Column 8, lines 21-27) and the surface has cationic polymer on the surface (Column 18, lines 3-8).

Regarding Claim 17, Fodor et al disclose the substrate wherein the sequences are genomic DNA sequences (e.g. Column 85, lines 25-37).

Regarding Claim 18, Fodor et al disclose the substrate has at least 2500 or more regions i.e. 10,000/cm<sup>2</sup> (Claim 42).

Regarding Claim 19, Fodor et al disclose the substrate has at least 10,000 regions (Claim 42).

Regarding Claim 21, Fodor et al disclose (and claim) a substrate comprising a microarray of DNA having a density of 400 or more regions/cm<sup>2</sup> wherein the DNA sequences are about 50 subunits in length (Claims 40 & 56). Fodor et al does not teach the method steps recited in the claim. However, the method steps do not result in any structural or compositional difference over the substrate of Fodor. Furthermore, the courts have stated that the process of making a product does not distinguish the product over the prior art.

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“[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113.

Regarding Claim 22, Fodor et al disclose the substrate wherein density is at least 10,000 regions/cm<sup>2</sup> (Claim 42).

Regarding Claim 23, Fodor et al disclose the substrate wherein density is at least 2500 i.e. 10,000 regions/cm<sup>2</sup> (Claim 42)

Regarding Claim 24, Fodor et al disclose the substrate wherein the substrate is glass (Claim 61).

Regarding Claim 25, Fodor et al disclose the substrate wherein the substrate is non-porous i.e. glass (Claim 61).

Regarding Claim 26, Fodor et al disclose the substrate wherein the surface is hydrophobic e.g. plastics or hydrophobic linkers (Column 17, lines 14-48).

Regarding Claim 27, Fodor et al disclose the substrate wherein the surface comprises one or more functional groups e.g. silyl, hydroxyl, carboxyl, amine aldehyde, sulhydryl (Column 17, lines 24-29).

Regarding Claim 29, Fodor et al disclose the substrate wherein the DNA sequences are covalently bound (Column 8, lines 21-27).

Regarding Claim 30, Fodor et al disclose the substrate wherein the DNA sequences are non-covalently bound (Column 8, lines 21-27).

Regarding Claim 31, Fodor et al disclose the substrate wherein the sequences are genomic DNA sequences (e.g. Column 85, lines 25-37).



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Regarding Claim 32, Fodor et al disclose the substrate has at least 2500 or more regions i.e. 10,000/cm<sup>2</sup> (Claim 42).

Regarding Claim 33, Fodor et al disclose the substrate has at least 10,000 regions (Claim 42).

Regarding Claim 34, Fodor et al disclose (and claim) a substrate comprising a microarray of DNA having a density of 400 or more regions/cm<sup>2</sup> wherein the DNA sequences are about 50 subunits in length and unique (i.e. different) in each region (Claims 40 & 56).

Regarding Claim 35, Fodor et al disclose the substrate of Claim 34. Fodor et al further teach the substrate is used for expression analysis (Column 66, lines 17-27). Fodor et al do not specifically teach detection of a two-fold change in abundance. However, the claimed detection is a recitation of intended use and the courts have stated that a recitation of intended use not distinguish a device over the prior art. Therefore, the detection does not further define the substrate of Claim 34.

A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Regarding Claim 36, Fodor et al disclose (and claim) a substrate comprising a microarray of DNA having a density of 400 or more regions/cm<sup>2</sup> wherein the DNA sequences are about 50 subunits in length and unique (i.e. different) in each region (Claims 40 & 56). Fodor et al further teach the substrate wherein the DNA sequences are non-covalently bound (Column 8, lines 21-27) and the surface has cationic polymer on the surface (Column 18, lines 3-8).

Regarding Claim 37, Fodor et al disclose the substrate wherein the DNA microarray is used to detect mRNA (e.g. Column 66, lines 17-27). Hence, the substrate comprises DNA complementary to mRNA i.e. cDNA.

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Regarding Claim 38, Fodor et al disclose the substrate wherein the DNA is used to detect distinct gene sequences (e.g. Column 117). Fodor et al further teach the gene sequences have expression levels different for control vs test e.g. alleles (Column 117, lines 20-49).

Regarding Claim 39, Fodor et al disclose the substrate wherein the DNA is used to detect distinct gene sequences (e.g. Column 117). Fodor et al further teach the gene sequences have expression levels different for control vs test e.g. alleles (Column 117, lines 20-49).

Regarding Claim 40, Fodor et al disclose the substrate wherein the regions are of a density between about 62,500 and 625 regions/cm<sup>2</sup> (e.g. 10<sup>4</sup>, 10<sup>5</sup>, 10<sup>6</sup> etc. regions, Column 21, lines 4-8).

10. Claims 7-15, 17-19, 21-27, 29-35, 38-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Winkler et al (U.S. Patent No. 5,677,195, filed 20 November 1992).

Regarding Claim 7, Winkler et al disclose (and claim) a substrate comprising a microarray of DNA having a density of 400 or more regions/cm<sup>2</sup> wherein the DNA sequences are about 50 subunits in length (Column 17, lines 49-57 and Column 18, lines 47-50).

Regarding Claim 8, Winkler et al disclose the substrate wherein density is at least 10,000 regions/cm<sup>2</sup> (Column 18, lines 47-50).

Regarding Claim 9, Winkler et al disclose the substrate wherein density is at least 2500 i.e. 10,000 regions/cm<sup>2</sup> (Column 18, lines 47-50)

Regarding Claim 10 Winkler et al disclose the substrate wherein the substrate is glass (Column 14, lines 45-46).

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Regarding Claim 11 Winkler et al disclose the substrate wherein the substrate is non-porous i.e. glass (Column 14, lines 45-46).

Regarding Claim 12, Winkler et al disclose the substrate wherein the surface is hydrophobic (Column 9, lines 50-56 and Column 22, lines 8-20).

Regarding Claim 13, Winkler et al disclose the substrate wherein the surface comprises one or more functional groups e.g. silyl, hydroxyl, carboxyl, amine aldehyde, sulhydryl (Column 23, lines 13-18).

Regarding Claim 14, Winkler et al disclose the substrate wherein the DNA sequences are covalently bound (Column 10, lines 43-47).

Regarding Claim 15, Winkler et al disclose the substrate wherein the DNA sequences are non-covalently bound (Column 5, lines 42-47 and Column 10, lines 43-47).

Regarding Claim 17, Winkler et al disclose the substrate wherein the sequences are DNA sequences (Column 6, lines 18-22) that are comprised of nucleotides A, T, G, C. The claims are drawn to fragments of genomic DNA, which encompasses combinations of as few as two A, T, G, C. Because the claims are drawn to as few as two A, T, G and/or C and because Winkler et al teach 50mers of A, T, G and/or C. Winkler is deemed to teach the sequences as claimed.

Regarding Claim 18, Winkler et al disclose the substrate has at least 2500 or more regions i.e. 10,000/cm<sup>2</sup> (Column 18, lines 47-50).

Regarding Claim 19, Winkler et al disclose the substrate has at least 10,000 regions (Column 18, lines 47-50).

Regarding Claim 21, Winkler et al disclose (and claim) a substrate comprising a microarray of DNA having a density of 400 or more regions/cm<sup>2</sup> wherein the DNA sequences are about 50 subunits in length (Column 17, lines 49-57 and Column 18, lines 47-50).

Winkler et al does not teach the method steps recited in the claim. However, the method steps do not result in any structural or compositional difference over the substrate of Winkler.

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Furthermore, as cited above, the courts have stated that the process of making a product does not distinguish the product over the prior art.

Regarding Claim 22, Winkler et al disclose the substrate wherein density is at least 10,000 regions/cm<sup>2</sup> (Column 18, lines 47-50).

Regarding Claim 23, Winkler et al disclose the substrate wherein density is at least 2500 i.e. 10,000 regions/cm<sup>2</sup> (Column 18, lines 47-50)

Regarding Claim 24 Winkler et al disclose the substrate wherein the substrate is glass (Column 14, lines 45-46).

Regarding Claim 25 Winkler et al disclose the substrate wherein the substrate is non-porous i.e. glass (Column 14, lines 45-46).

Regarding Claim 26, Winkler et al disclose the substrate wherein the surface is hydrophobic (Column 9, lines 50-56 and Column 22, lines 8-20).

Regarding Claim 27, Winkler et al disclose the substrate wherein the surface comprises one or more functional groups e.g. silyl, hydroxyl, carboxyl, amine aldehyde, sulhydryl (Column 23, lines 13-18).

Regarding Claim 29, Winkler et al disclose the substrate wherein the DNA sequences are covalently bound (Column 10, lines 43-47).

Regarding Claim 30, Winkler et al disclose the substrate wherein the DNA sequences are non-covalently bound (Column 5, lines 42-47 and Column 10, lines 43-47).

Regarding Claim 31, Winkler et al disclose the substrate wherein the sequences are DNA sequences (Column 6, lines 18-22), which are, comprised of nucleotides A, T, G, C. The claims are drawn to fragments of genomic DNA that encompasses combinations of as few as two A, T, G, C. Because the claims are drawn to as few as two A, T, G and/or C and because Winkler et al teach 50mers of A, T, G and/or C. Winkler is deemed to teach the sequences as claimed.

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Regarding Claim 32, Winkler et al disclose the substrate wherein density is at least 2500 i.e. 10,000 regions/cm<sup>2</sup> (Column 18, lines 47-50)

Regarding Claim 33, Winkler et al disclose the substrate wherein density is at least 10,000 regions/cm<sup>2</sup> (Column 18, lines 47-50).

Regarding Claim 34, Winkler et al disclose (and claim) a substrate comprising a microarray of DNA having a density of 400 or more regions/cm<sup>2</sup> wherein the DNA sequences are about 50 subunits in length (Column 17, lines 49-57 and Column 18, lines 47-50). Winkler et al does not teach the method steps recited in the claim. However, the claimed selective hybridization is a recitation of intended use and, as cited above, the courts have stated that a recitation of intended use not distinguish a device over the prior art. Therefore, the detection does not further define the substrate.

Regarding Claim 35, Winkler et al disclose the substrate of Claim 34 but do not teach the detection as recited in the claim. However, the claimed detection is a recitation of intended use and the courts have stated that a recitation of intended use not distinguish a device over the prior art. Therefore, the detection does not further define the substrate of Claim 34.

Regarding Claim 38, Winkler et al disclose the substrate wherein the DNA is used to detect distinct sequences wherein relative binding is analyzed (e.g. Column 7, line 43-Column 8, line 7).

Regarding Claim 39, Winkler et al disclose the substrate wherein the DNA is used to detect distinct sequences wherein relative binding is analyzed (e.g. Column 7, line 43-Column 8, line 7).

Regarding Claim 40, Winkler et al disclose the substrate wherein the regions are of a density between about 62,500 and 625 regions/cm<sup>2</sup> (e.g. 10,000 regions, Column 18, lines 43-50).

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### **Conclusion**

11. No claim is allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



BJ Forman, Ph.D.  
Primary Examiner  
Art Unit: 1634  
March 9, 2006